

09/438,676

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	BLACH ET AL.	Examiner:	G. DAWSON
Serial No.:	09/438,676	Group Art Unit:	3731
Filed:	NOVEMBER 12, 1999	Docket No.:	12460.1USC4
Title:	NASAL SUPPORT DEVICE FOR DOMESTIC MAMMALS AND METHOD		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited in the United States Postal Service, as first class mail, with sufficient postage, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on APR 11 4, 2005.

By:

Name:

Kristine A. Wallace
Kristine A. Wallace

DECLARATION OF HOWARD H. ERICKSON DVM, PhD

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I Howard H. Erickson declare as follows:

1. I am Professor of Physiology in the Department of Anatomy and Physiology at the College of Veterinary Medicine at Kansas State University, Manhattan Kansas.
2. I received my Doctor of Veterinary Medicine (DVM) degree in 1959 from Kansas State University and my PhD (a major in physiology and minors in biomedical engineering and biochemistry) in 1966 from Iowa State University. Prior to graduate school I was in private practice and after graduate school I have held various positions as a veterinary physiologist for the USAF and faculty member at Colorado State and Texas A& M Universities and University of Texas Health Science Center in San Antonio.
3. I am the author or co-author of over 160 scientific research articles or text book chapters. The majority of my research and publications are in the field of animal physiology,

particularly dealing with cardiopulmonary physiology. I have conducted significant research in the area of equine exercise and cardiopulmonary physiology. I have also conducted significant research and published over 50 scientific articles in the area of exercise-induced pulmonary hemorrhage (EIPH) in horses.

4. I am familiar with equine nasal support devices and in particular with the FLAIR® Equine Nasal Strip commercialized by CNS, Inc. (CNS) in 1999, which I understand is a device for use according to the method of the invention of the above referenced patent application. Prior to learning of the FLAIR Strip from CNS in early 1999, I was unaware of nasal support devices for horses or that they could be used to facilitate air flow or ameliorate respiratory conditions in horses. I was familiar with the Breathe Right® nasal strip for humans that was commercialized by CNS prior to learning of the FLAIR Strips.

5. I have conducted clinical research at Kansas State University regarding FLAIR Strips beginning in early 1999 and have published over 10 articles discussing the beneficial effect of using equine nasal supports for reducing EIPH in horses.

6. I have read and understand the subject matter of U.S. Patent No. 6,470,883 to Beaudry ("Beaudry"). Beaudry discloses devices used for a variety of purposes including, "dressings for wounds, bandages, drug delivery systems, epidermal lifting mechanisms, and positioning mechanisms for positioning epidermal layers of skin on humans and/or animals in predetermined manner." Beaudry at col. 1, lines 11-14. Beaudry discloses epidermal lifting mechanisms and methods for increasing the flow of gases into the human body..." Beaudry at col. 1, lines 18-20. I do not understand Beaudry to disclose or suggest the use of a nasal epidermal lifting mechanism on animals, and particularly not on horses.

7. Moreover, it is incorrect to assume that because a nasal dilator used on human beings may have efficacy in reducing resistance to air inflow that the same is true for animals. Not only are there significant facial anatomic differences between humans and animals, in addition, the presence of the eqine nasal diverticulum would not make the use of such a device on horses obvious. Indeed, to the extent a nasal support device could provide benefit to a horse, it would be essential to have a clear understanding of the proper construction and positioning of such a device on a horse. Neither is provided by Beaudry.

8. I have read and understand the subject matter of the article by W. Robert Cook, FRCVS, PhD, "EIPH or AIPE, A Tufts University Researcher suggests that bleeding is not

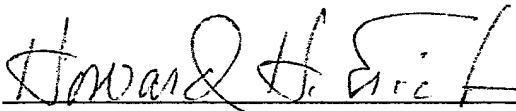
caused by EIPH, but by asphyxia" *Equine Athlete*, p.22-23 (March/April 1997) ("Cook Article"). I am familiar with the airway resistance work of Dr. Robert Cook. In the Cook Article, Cook proposed a theory that pulmonary edema was caused by asphyxia due to a closed upper airway. This theory by Cook and the remainder of the Cook article fail to teach or suggest that support of the tissue overlying the nasal passages would reduce EIPH in horses. Everything in the Cook Article theorizes a problem in the throat region of the upper airway, and in particular due to a condition referred to as recurrent laryngeal neuropathy. The Cook Article provides absolutely no basis for believing that merely supporting physiologically normal tissue overlying the nasal passages could reduce EIPH in horses.

9. It is my opinion that even if Beaudry is considered to teach the use of a nasal epidermal dilator for use in an animal, that teaching combined with the Cook Article does not teach or suggest that support of the nasal tissue overlying the nasal passages will reduce EIPH in horses. Nor do these combined references make obvious the use of nasal support devices to ameliorate any other conditions of the equine airway.

10. In fact, even after CNS disclosed the FLAIR Strip to me and asked me to conduct studies on horses to determine whether the device reduced EIPH, I was skeptical. It definitely was not obvious to me that such a device would provide such a benefit as I now have learned to be the case.

11. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: March 10, 2005

Signed: 

Name: Howard H. Erickson, DVM, PhD